

**REMARKS**

This paper is provided in response to the Office Action dated March 1, 2004. Presently, claims 1-18 and 20-46 are pending. Claims 16-18 and 20-23 have been allowed, and claims 1-15 and 24-46 presently stand rejected. New claim 47 is added. Applicants appreciate the Examiner's indication of allowable subject matter in this application.

Claims 1, 3, 7-9, 11, 26 and 32 have been rejected under 35 USC 102(b) as anticipated by, or in the alternative, under 35 USC 103(a) as obvious over Drost et al (USP 6,036,645) ("Drost"). Claims 2 and 31 were rejected under 35 U.S.C. §103(a) as being unpatentable over Drost. Applicants respectfully traverse these rejections.

The present application is directed to a Doppler probe for detecting or measuring blood flow in a vessel. A key feature of the invention lies in the use of a shapeable probe portion (16 in Fig. 1) that allows a physician to customize the configuration of the portion of the device that is introduced into the patient, and specifically, into the natural spaces within the brain. The shapeable portion is plastically deformable into a desired contour by an operator immediately prior to the medical procedure, and is capable of holding its new shape as it is being manipulated within the patient. If necessary, the shapeable portion is also capable of further manipulation to assume additional new shapes as needed during the course of a normal medical procedure. See, e.g., page 9, lines 3-19 of the present application. The portion of the probe that extends distally from the handle is generally defined as the shapeable portion, however the shapeable part of the probe need not necessarily extend all the way to the handle. Page 6, lines 15-20.

Drost is directed to an ultrasonic probe that is used to measure arteries and veins that are exposed during surgery. (Col. 1, lines 6-8.) The probe includes a stiff portion 14 that comprises three elongated stiff sections 18, 20, 22. A flexible portion 16 extends in the distal direction from the distal end of stiff section 22, and a sensor 24 is connected to the distal end of flexible portion 16. Flexible portion 16 is not capable of maintaining its configuration, but rather, is provided in combination with a malleable guide wire that is capable of holding its position once set. Col. 3, lines 5-10. The relative alignment of stiff sections 18, 20, 22 is pre-determined by the manufacturer, and such sections are not subject to further manipulation and shaping by the operator. Specifically, sections 18, 20,

22 are aligned relative to the handle, and to each other, in a very specific configuration so that the handle does not block the surgeon's view of the sensor head when the device is in use.

The device of the present invention has features that are neither taught nor suggested by the Drost patent. For example, the inventive device includes a shapeable portion that is "sized and dimensioned for introduction into natural spaces of the brain to monitor flow through a vessel located therein". Further, according to claim 1, as amended, the shapeable portion extends proximally from adjacent the distal end of the probe and extends substantially to the handle. As a result, the operator can manipulate the shapeable portion substantially to the handle portion to conform to the natural spaces of the brain.

Thus, the inventive device is capable of manipulation by the operator. This allows the operator, for example, to establish whether an aneurysm clip has been properly applied to an affected cerebral vessel. Such use requires that the device be sufficiently ductile so that the operator can manipulate the shapeable portion to the necessary shape to achieve the desired pathway to the target site. The Drost device is not "sized and shaped" in this manner, and would not permit such use. Rather, the Drost device has a pre-set configuration virtually all the way from the handle to the distal end. Since the device is intended for use in measuring blood flow in exposed arteries and veins, it is generally not necessary to shape the device to conform to inner passageways in the manner of the inventive device, and perhaps, the Drost device is satisfactory for its intended uses. However, only a small distal portion of the Drost probe is deformable. It appears that at least a portion of the stiff section of Drost is intended to enter the body tissue, whereas in the inventive device virtually everything that is introduced into the body is shapeable. As a result, the utility and versatility of this device is much less than that of the claimed device, since the Drost device is only capable of manipulation within a very small range. The claimed device is capable of manipulation substantially to the handle, which allows use of the device in complex bodily passageways in which the Drost device could not be introduced. The stiff neck portion of the Drost device is perhaps of little concern when the device is to be used to measure blood flow in the exposed arteries and veins described in Drost. However, this device would not be appropriate for introduction into the tortuous passageways present in the natural spaces in the brain. One skilled in the art seeking to

develop a device for introduction into these natural spaces would not likely look to the teachings of Drost for guidance, because the stiff multi-sectional configuration of Drost would not be expected to have this utility.

Claims 1, 4 and 27-28 were rejected under 35 U.S.C. §103(a) as being unpatentable over Drost as applied to claims 1 and 7 above, and further in view of Gade (USP 4,945,896). The Gade reference was applied for teaching a bloodflow sensor in neurological brain procedures, and for teaching the housing of a blood flow sensor within a malleable probe portion. Gade is directed to a surgical retraction assembly for retracting and holding soft body tissue in a stationary retracted position. It does not teach or suggest a medical probe as claimed, nor is it combinable with Drost to obviate the recited claims. In particular, neither Drost nor Gade, either individually or in combination, teaches or suggests providing a shapeable portion of a medical probe that extends substantially to the probe handle (claims 1, 4) or that extends distally from the proximal end of the probe (claims 27, 28).

Claims 4-6, 29-30 and 33-40 were rejected under 35 U.S.C. §103(a) as being unpatentable over Drost as applied to claims 1 and 26 above, and further in view of Yock, et al.. Yock was applied for teaching the housing of transducer within a probe portion during an invasive procedure, and for teaching encasement of a probe within epoxy. Claims 4-6 depend, directly or indirectly, from claim 1 and include all of its limitations. Claims 29-30 depend, directly or indirectly, from claim 26 and include all of its limitations. Claim 33 is an independent claim, and claims 34-40 depend, directly or indirectly, from claim 33 and include all of its limitations. Independent claim 33 differs from previous independent claims, in pertinent part for purposes of this rejection, because the transducer head of claim 33 includes an encasing material surrounding the transducer. Yock, however, does not supply the features missing from the Drost reference, as discussed above. Thus, these claims are allowable for at least the same reasons that claims 1-3, 7-9, 11, 26, 31 and 32 are allowable.

Claims 10-12 were rejected under 35 U.S.C. §103(a) as being unpatentable over Drost as applied to claim 9 above, and further in view of Salmon, et al. (USP 5,503,155). Claim 13 was rejected under 35 U.S.C. §103(a) as being unpatentable over Drost as applied to claim 1 above, and further in view of Chandler et al. (USP 6,093,150). Claims 14-15 were rejected under 35 U.S.C. §103(a) as being unpatentable over Drost in view of

Chandler et al. as applied to claim 14 above, and further in view of McLeod (USP 4,142,412). Claim 24 was rejected under 35 U.S.C. §103(a) as being unpatentable over Drost as applied to claim 1 above, and further in view of Boykin (USP 5,360,406).

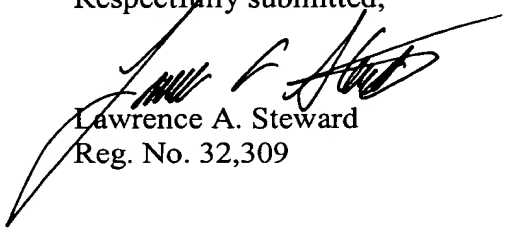
All of these claims (10-15 and 24) depend, directly or indirectly, from claim 1 and include all of its limitations, including the limitation of a shapeable probe portion as previously described. Salmon was cited for teaching shapeable wire. Chandler was cited for teaching a plurality of transducers, and McLeod was cited for teaching a particular orientation of a pair of transducers. Boykin was cited for teaching an annealed wire. These references, however, do not supply the features missing from the Drost reference, and particularly, do not teach or suggest providing a shapeable portion of a medical probe that extends substantially to the probe handle, as discussed above. Thus, these claims are allowable for at least the same reasons that the aforementioned claims are allowable.

Claim 36 was rejected under 35 U.S.C. §103(a) as being unpatentable over Drost in view of Yock as applied to claim 33 above, and further in view of Gade. Claims 41-43 were rejected under 35 U.S.C. §103(a) as being unpatentable over Drost in view of Yock as applied to claim 40 above, and further in view of Salmon. Claim 44 was rejected under 35 U.S.C. §103(a) as being unpatentable over Drost in view of Yock as applied to claim 33, and further in view of Chandler et al. as the latter was applied regarding claim 13. Claims 45-46 were rejected under 35 U.S.C. §103(a) as being unpatentable over Drost in view of Yock and Chandler et al. as applied to claim 44 above, and further in view of McLeod, as the latter was applied against claims 14-15.

Claims 36 and 41-46 depend, directly or indirectly, from independent claim 33, and include all of its limitations, including the limitation of a probe having a shapeable portion that extends distally from a handle portion. The secondary references do not teach or suggest such a feature, and accordingly, these claims are allowable for the same reasons that claim 33 is allowable.

Based on the foregoing, Applicants respectfully submit that all claims 1-18 and 20-47 are in condition for allowance and accordingly, request the prompt issuance of a Notice of Allowance in this matter. If the Examiner believes that there are any issues left for consideration, the Examiner is respectfully invited to telephone the undersigned attorney.

Respectfully submitted,



Lawrence A. Steward  
Reg. No. 32,309

LAS/cbw

BRINKS HOFER GILSON & LIONE  
One Indiana Square, Suite 1600  
Indianapolis, Indiana 46204-2033  
Telephone: (317) 636-0886  
Fax: (317) 634-6701